K112405

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CLYDESDALE® Spinal System
510(k) Summary
August 2011

NOV 2 1 2011

I. **Company:** **Medtronic Sofamor Danek**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

Contact: **Julie Bassett**
Sr. Regulatory Affairs Specialist

II. **Proprietary Trade Name: CLYDESDALE® Spinal System**

III. **Classification Name:** Intervertebral Body Fusion Device (21 CFR 888.3080)

IV. **Product Code: MAX**

V. **Product Description**

The CLYDESDALE® Spinal System consists of a variety of hollow vertebral body spacers featuring a convex, bullet-nosed interbody device designed with an axial void to contain autogenous graft material, and facilitate a fusion between two vertebral bodies. This device is designed with angular teeth to allow the implant to grip the superior and inferior end plates, thus allowing expulsion resistance. The device is manufactured from medical grade polyetheretherketone (PEEK) Optima 1 and includes Tantalum markers for imaging purposes and provided sterile by gamma irradiation. The predicate device is available in a variety of sizes ranging from 8mm to 16mm in height and 40mm to 60mm in length. The purpose of this submission is to add a new Direct Lateral (DL) Inserter instrument to be used with the CLYDESDALE® Spinal System.

VI. Indications

The CLYDESDALE® Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CLYDESDALE® Spinal System is used for patients diagnosed with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a minimally invasive lateral approach.

VII. Substantial Equivalence

Documentation was provided which demonstrated that the subject CLYDESDALE® Spinal System device is substantially equivalent to the predicate CLYDESDALE® Spinal System device cleared in K083026 (SE 12/29/2008) &K100175 (SE 06/02/10).

VIII. Brief Discussion of the Non-Clinical Tests Submitted

A new Direct Lateral (DL) Inserter instrument was added to the CLYDESDALE® Spinal System and reprocessing instructions for the new instrument were added to the labeling. The subject and predicate CLYDESDALE® Spinal System devices are identical in terms of indications for use, intended use, performance specifications, and technological characteristics. Assessment of the dimensional modifications has been completed in accordance with internal Medtronic processes. Cleaning and sterilization assessments have been conducted to provide the appropriate disassembly, reassembly, cleaning, and sterilization instructions for the CLYDESDALE® Spinal System.

IX. Conclusions Drawn from the Non-Clinical Tests

Medtronic believes the information above demonstrates equivalence and supports a determination of substantial equivalence between the subject and predicate CLYDESDALE® Spinal System devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 2 1 2011

Medtronic Sofamor Danek
% Ms. Julie Bassett
Sr. Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K112405
Trade/Device Name: CLYDESDALE® Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: October 21, 2011
Received: October 24, 2011

Dear Ms. Bassett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices; good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K112405

Device Name: CLYDESDALE® Spinal System

Indications for Use:

The CLYDESDALE® Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CLYDESDALE® Spinal System is used for patients diagnosed with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a minimally invasive lateral approach.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112405